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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) Long, et al. Examiner: Unassigned
Serial No.: 10/797,747 Group Art Unit: 1617
Confirmation No: 3427 Docket: 1341-3
Filed: March 10, 2004 Dated: July 6, 2004
For: THERAPEUTIC, NUTRACEUTICAL
AND COSMETIC APPLICATIONS
FOR EGG SHELL MEMBRANE AND
PROCESSED EGG SHELL
MEMBRANE PREPARATIONS

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

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on July 6, 2004*

Signed: Joyce Peterson

INFORMATION DISCLOSURE STATEMENT

Sir:

In order to fulfill the requirements of candor and good faith set forth in 37 C.F.R.

§1.56, Applicants submit herewith the following Information Disclosure Statement in
accordance with the provisions of 37 C.F.R. §1.97 and §1.98.

UNITED STATES PATENT PUBLICATIONS

<u>PATENTEE</u>	<u>PUBLICATION NO.</u>	<u>PUBLICATION DATE</u>
Brown et al.	2002/0037312 A1	March 28, 2002
Brown et al.	2003/0175332 A1	September 18, 2003

UNITED STATES PATENTS

<u>PATENTEE</u>	<u>PATENT NO.</u>	<u>ISSUE DATE</u>
Neuhauser	3,194,732	July 13, 1965
Balazs	4,141,973	February 27, 1979
Bracke et al.	4,517,295	May 14, 1985
Balazs et al.	4,713,448	December 15, 1987
Sakurai et al.	4,716,224	December 29, 1987
Nimrod et al.	4,784,990	November 15, 1988
Cullis-Hill	4,879,375	November 7, 1989
Diot et al.	4,992,264	February 12, 1991
Drizen et al.	5,079,236	January 7, 1992
Balazs et al.	5,099,013	March 24, 1992
Noel	5,141,964	August 25, 1992
della Valle et al.	5,166,331	November 24, 1992
Brown et al.	5,316,926	May 31, 1994
Ellwood et al.	5,411,874	May 2, 1995
Kakoki et al.	5,415,875	May 16, 1995
Abad	5,538,740	July 23, 1996
Yamaguchi et al.	5,460,832	October 24, 1995
Romeo et al.	5,559,104	September 24, 1996
Callegaro et al.	5,646,129	July 8, 1997
Mälson et al.	5,783,691	July 21, 1998
della Valle et al.	5,925,626	July 20, 1999
Lezdey et al.	5,869,063	February 9, 1999
Moy	5,928,659	July 27, 1999

<u>PATENTEE</u>	<u>PATENT NO.</u>	<u>ISSUE DATE</u>
Burns et al.	6,030,958	February 29, 2000
Stahl	6,090,596	July 18, 2000
Falk et al.	6,194,392 B1	February 27, 2001
Mohammadi	6,217,913 B1	April 17, 2001
Falk et al.	6,218,373 B1	April 17, 2001
Henderson et al.	6,255,295 B1	July 3, 2001
Wolfenbarger, Jr.	6,337,389 B1	January 8, 2002
Pillai et al.	6,399,083 B1	June 4, 2002
Ubara	6,498,204 B1	December 24, 2002

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<u>COUNTRY</u>	<u>PUBLICATION NO.</u>	<u>PUBLICATION DATE</u>
Japan	JP1043502	February 15, 1989

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1. Nakano T., Ikawa NI, Ozimek., "Chemical composition of chicken eggshell and shell membranes," *Poult Sci.* 2003, 82(3):510-4 [Abstract].
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3. Hincke MT, Gautron J., Panheleux M., Garcia-Ruiz J., McKee MD, Nys Y., "Identification and localization of lysozyme as a component of eggshell membranes and eggshell matrix," *Matrix Biol* 2000, 19(5):443-53 [Abstract].
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5. Arias JL, Nakamura O, Fernandez MS, Wu JJ, Knigge P, Eyre DR, Caplan AI, "Role of type X collagen on experimental mineralization of eggshell membranes," *Connect Tissue Res* 1997, 36(1):21-33.

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6. Arias JL, Fernandez MS, Dennis JE, Caplan AI, "Collagens of the chicken eggshell membrane," *Connect Tissue Res* 1991, 26(1-2):37-45 [Abstract].
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8. Osuoji CI, "Acid glycosaminoglycan of eggshell membranes," *Biochim Biophys Acta* 1971, 244(2):481-3.
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11. Suyama K, Fukazawa Y, Umetsu Y, "A new biomaterial, hen egg shell membrane, to eliminate heavy metal ion from their dilute waste solution," *Appl Biochem Biotechnol* 1994, 45-46:871-9[Abstract].
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13. U.S. Department of Agriculture, Avian Physiology Laboratory, Beltsville, Maryland 20705, "Levels of calcium and soluble collagen in turkey egg shell membranes," *Comp Biochem Physiol A* 1988, 90(3):421-4[Abstract].
14. Leach RM Jr, Rucker RB, Van Dyke GP, "Egg shell membrane protein: a nonelastin desmosine/isodesmosine-containing protein," *Arch Biochem Biophys* 1981, 207(2):353-9[Abstract].
15. Crombie G, Snider R, Faris B, Franzblau C, "Lysine-derived cross-links in the egg shell membrane," *Biochim Biophys Acta* 1981, 640(1):365-7[Abstract].
16. Harris ED, Blount JE, Leach RM Jr., "Localization of lysyl oxidase in hen oviduct: implications in egg shell membrane formation and composition," *Science* 1980, 208(4439):55-6[Abstract].
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19. Robinson DS, King NR, "Mucopolysaccharides of an avian egg shell membrane," *JR Microsc Soc* 1968, 88(1):13-22[Abstract].

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20. Powrie William, Nakai S., "The Chemistry of eggs and egg products," *Egg Science and Technology* 1990, 97-139.
21. Wu Tzong-Ming, Rodriguez Juan Pablo, Fink David, Carrino David, Blackwell John, Caplan Arnold, Heuer Arthur, "Crystallization Studies on Avian Eggshell Membranes: Implications for the Molecular Factors Controlling Eggshell Formation," *Matrix Biology* 1995, 14:507-513.
22. Wong Mitchell, Hendrix Mary J.C., Mark Klaus von der, Little Charles, Stern Robert, "Collagen in the Egg Shell Membrane of the Hen," *Developmental Biology* 1984 104:28-36.
23. Gautron, Bain M., Solomon S, NYS Y., "Soluble matrix of hen's eggshell extracts changes *in vitro* the rate of calcium carbonate precipitation and crystal morphology," *British Poultry Science* 1996 37, 853-866.
24. Tomihata Kenji, Ikada Yoshito, "Crosslinking of hyaluronic acid with water-soluble carbodiimide," *J Biomed Mater Res*, 1997, 37, 243-251.
25. Carrino David, Dennis James, Wu Tzong-Ming, Arias Jose, Fernandez Maria, Rodriguez Juan, Fink David, Heuer Arthur, Caplan Arnold, "The Avian Eggshell Extracellular Matrix as a Model for Biomineralization," *Connective Tissue Research*, 1996, 35(1-4), 325-329.
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28. "Egg Science and Technology", Eds. W.J. Stadelman and O.J. Cotterill, Food Products Press, a subsidiary of The Haworth Press, Bingham, NY, 1990.
29. Britton, W.M. and Hale, K.K., "Amino Acid Analysis of Shell Membranes of Eggs from Young and Old Hens Varying in Shell Quality", *Poultry Science*, 56:865-871, 1977.
30. Cifonelli, J.A., "The Colormetric Estimation of Uronic Acid", *Methodology of Connective Tissue Research*, ED:DA Hall, Joynson-Bruvvers Ltd., Oxford, 1976, Chapter 26, pp. 253-256.
31. Armstrong, DC and Johns, MR, "Improved Molecular Weight Analysis of Streptococcal Hyaluronic Acid by Size Exclusion Chromatography" in *Biotechnology Techniques*.

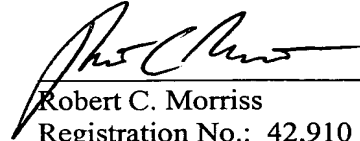
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32. Fernandez, M.S., Araya, M., and Arias, JL, "Eggshells are Shaped by a Precise Spatio-Temporal Arrangement of Sequentially Deposited Macromolecules", *Matrix Biol.*, 16:13-20, 1997.
33. Takahashi, K., Shirai, K., Kitamura, M., Hattori, M., "Soluble Egg Shell Membrane Protein as a Regulating Material for Collagen Matrix Reconstruction", *Biosci. Biotechnology & Biochemistry*, 60:1299-1302, 1996.
34. T.C. Laurent, "Structure of Hyaluronic Acid", *Chem. and Mol. Biol. of Intracellular Matrix*, Vol. 2, 1970, pp. 703-732.
35. O.H. Lowry et al., "Protein Measurement with the Folin Phenol Reagent", *The Journal of Biological Chemistry*, Vol. 193 (1951) pp. 265-275.
36. W.D. Comper et al., "Physiological Function of Connective Tissue Polysaccharides", *Physiological Reviews*, Vol. 58, No. 1 (1978) pp. 255-315.
37. K. Meyer, "Chemical Structure of Hyaluronic Acid", *Fed. Proceed*, Vol. 17 (1958) pp. 1075-1077.
38. E.A. Balazs et al., "Hyaluronic Acid and Replacement of Vitreous and Aqueous Humor", *Mod. Probl. Ophthal.*, Vol. 10 (1972) pp. 3-21.
39. U.B.G. Laurent, "Hyaluronate in Human Aqueous Humor", *Arch Ophtalmol.*, Vol. 101 (1983) pp. 129-130., Vol. 101 (1983) pp. 129-130.

The above-referenced documents are listed on PTO Form 1449. We have enclosed the cited documents to facilitate reference to them, with the exception of Powrie William, Nakai S., "The Chemistry of eggs and egg products," *Egg Science and Technology*, which will be provided shortly. Additionally, an English abstract has been provided for Japanese Publication No. JP1043502.

Applicants are not aware of any other references to be identified at this time. If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact Applicants' attorney at the telephone number set forth below.

Respectfully submitted,



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FORM PTO-1449
(Rev. 2-32)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
1341-3SERIAL NO.
10/797,747INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
Long, et al.CONFIRMATION NO.
3427

(Use several sheets if necessary)

FILING DATE
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U.S. PATENT PUBLICATIONS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
		2002/0037 312 A1	03/28/02	Brown et al.			
		2003/0175 332A1	09/18/03	Brown et al.			

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
		3,194,732	07/13/65	Neuhauser			
		4,141,973	02/27/79	Balazs			
		4,517,295	05/14/85	Bracke et al.			
		4,713,448	12/15/87	Balazs et al.			
		4,716,224	12/29/87	Sakurai et al.			
		4,784,990	11/15/88	Nimrod et al.			
		4,879,375	11/07/89	Cullis-Hill			
		4,992,264	02/12/91	Diot et al.			
		5,079,236	01/07/92	Drizen et al.			
		5,099,013	03/24/92	Balazs et al.			
		5,141,964	08/25/92	Noel			
		5,166,331	11/24/92	Della Valle et al.			
		5,316,926	05/31/94	Brown et al.			
		5,411,874	05/02/95	Ellwood et al.			

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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Rev. 2-32) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	ATTY. DOCKET NO. 1341-3	SERIAL NO. 10/797,747
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		5,415,875	05/16/95	Kakoki et al.			
		5,538,740	07/23/96	Abad			
		5,460,832	10/24/95	Yamaguchi et al.			
		5,559,104	09/24/96	Romeo et al.			
		5,646,129	07/08/97	Callegaro et al.			
		5,783,691	07/21/98	Malson et al.			
		5,925,626	07/20/99	Della Valle et al.			
		5,869,063	02/09/99	Lezdey et al.			
		5,928,659	07/27/99	Moy			
		6,030,958	02/29/00	Burns et al.			
		6,090,596	07/18/00	Stahl			
		6,194,392 B1	02/27/01	Falk et al.			
		6,217,913 B1	04/17/01	Mohammadi			
		6,218,373 B1	04/17/01	Falk et al.			
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
							YES	NO
		JP1043502	02/15/89	Japan				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

			Nakano T., Ikawa NI, Ozimek, "Chemical composition of chicken eggshell and shell membranes," <i>Poult Sci.</i> 2003, 82(3):510-4 [Abstract].
			Dupoirieux L., Pourquoi D., Picot MC, Neves M., "Comparative study of three different membranes for guided bone regeneration of rat cranial defects," <i>Int J Oral Maxillofac Surg</i> 2001, 30(1):58-62 [Abstract].
			Hincke MT, Gautron J., Panheleux M., Garcia-Ruiz J., McKee MD, Nys Y., "Identification and localization of lysozyme as a component of eggshell membranes and eggshell matrix," <i>Matrix Biol</i> 2000, 19(5):443-53 [Abstract].
			Dupoirieux L., Neves M., Pourquoi D., "Comparison of pericranium and eggshell as space fillers used in combination with guided bone regeneration: an experimental study," <i>J Oral Maxillofac Surg</i> 2000, 58(1):40-6 [Abstract].
			Arias JL, Nakamura O, Fernandez MS, Wu JJ, Knigge P, Eyre DR, Caplan AI, "Role of type X collagen on experimental mineralization of eggshell membranes," <i>Connect Tissue Res</i> 1997, 36(1):21-33.
			Arias JL, Fernandez MS, Dennis JE, Caplan AI, "Collagens of the chicken eggshell membrane," <i>Connect Tissue Res</i> 1991, 26(1-2):37-45 [Abstract].
			Starcher BC, King GS, "The presence of desmosine and isodesmosine in eggshell membrane protein," <i>Connect Tissue Res</i> 1980, 8(1):53-5 [Abstract].
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		Akagawa M, Wako Y, Suyama K, "Lysyl oxidase coupled with catalase in egg shell membrane," <i>Biochim Biophys Acta</i> 1999, 1434(1):151-60 [Abstract].
		Suyama K, Fukazawa Y, Umetsu Y, "A new biomaterial, hen egg shell membrane, to eliminate heavy metal ion from their dilute waste solution," <i>Appl Biochem Biotechnol</i> 1994, 45-46:871-9[Abstract].
		Arias JL, Fernandez MS, Dennis JE, Caplan AL, "The fabrication and collagenous substructure of the eggshell membrane in the isthmus of the hen oviduct," <i>Matrix</i> 1991, 11(5):313-20[Abstract].
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		Leach RM Jr, Rucker RB, Van Dyke GP, "Egg shell membrane protein: a nonelastin-desmosine/isodesmosine-containing protein," <i>Arch Biochem Biophys</i> 1981, 207(2):353-9[Abstract].
		Crombie G, Snider R, Faris B, Franzblau C, "Lysine-derived cross-links in the egg shell membrane," <i>Biochim Biophys Acta</i> 1981, 640(1):365-7[Abstract].
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			Robinson DS, King NR, "Mucopolysaccharides of an avian egg shell membrane," <i>JR Microsc Soc</i> 1968, 88(1):13-22[Abstract].
			Powrie William, Nakai S., "The Chemistry of eggs and egg products," <i>Egg Science and Technology</i> 1990, 97-139.
			Wu Tzong-Ming, Rodriguez Juan Pablo, Fink David, Carrino David, Blackwell John, Caplan Arnold, Heuer Arthur, "Crystallization Studies on Avian Eggshell Membranes: Implications for the Molecular Factors Controlling Eggshell Formation," <i>Matrix Biology</i> 1995, 14:507-513.
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			Tomihata Kenji, Ikada Yoshito, "Crosslinking of hyaluronic acid with water-soluble carbodiimide," <i>J Biomed Mater Res</i> , 1997, 37, 243-251.
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			Baker, J.R. et al., "A Study of the Organic Material of Hen's-Egg Shell", <i>Biochemical Journal</i> , 1962, 82, 352-361.
			"Egg Science and Technology", Eds. W.J. Stadelman and O.J. Cotterill, Food Products Press, a subsidiary of The Haworth Press, Bingham, NY, 1990.
			Britton, W.M. and Hale, K.K., "Amino Acid Analysis of Shell Membranes of Eggs from Young and Old Hens Varying in Shell Quality", <i>Poultry Science</i> , 56:865-871, 1977.
			Cifonelli, J.A., "The Colormetric Estimation of Uronic Acid", <i>Methodology of Connective Tissue Research</i> , ED:DA Hall, Joynson-Bruvvers Ltd., Oxford, 1976, Chapter 26, pp. 253-256.
			Armstrong, DC and Johns, MR, "Improved Molecular Weight Analysis of Streptococcal Hyaluronic Acid by Size Exclusion Chromatography" in <i>Biotechnology Techniques</i> .
			Fernandez, M.S., Araya, M., and Arias, JL, "Eggshells are Shaped by a Precise Spatio-Temporal Arrangement of Sequentially Deposited Macromolecules", <i>Matrix. Biol.</i> , 16:13-20, 1997.
			Takahashi, K., Shirai, K., Kitamura, M., Hattori, M., "Soluble Egg Shell Membrane Protein as a Regulating Material for Collagen Matrix Reconstruction", <i>Biosci. Biotechnology & Biochemistry</i> , 60:1299-1302, 1996.
			T.C. Laurent, "Structure of Hyaluronic Acid", <i>Chem. and Mol. Biol. of Intracellular Matrix</i> , Vol. 2, 1970, pp. 703-732.
			O.H. Lowry et al., "Protein Measurement with the Folin Phenol Reagent", <i>The Journal of Biological Chemistry</i> , Vol. 193 (1951) pp. 265-275.
			W.D. Comper et al., "Physiological Function of Connective Tissue Polysaccharides" <i>Physiological Reviews</i> , Vol. 58, No. 1 (1978) pp. 255-315.

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			K. Meyer, "Chemical Structure of Hyaluronic Acid", <i>Fed. Proceed</i> , Vol. 17 (1958) pp. 1075-1077.
			E.A. Balazs et al., "Hyaluronic Acid and Replacement of Vitreous and Aqueous Humor" <i>Mod. Probl. Ophthal.</i> , Vol. 10 (1972) pp. 3-21.
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EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.